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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,217	02/14/2002	Shai N. Gozani	NEURO-NRO-008	8764

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/075,217	Applicant(s) GOZANI ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41,42 and 45-47 is/are allowed.
- 6) ☒ Claim(s) 1-9,13,16-19,22-40,43,44 and 48-60 is/are rejected.
- 7) ☒ Claim(s) 10-12,14,15,20 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05042004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed September 20, 2004. The Examiner acknowledges the amendments to claims 1-3, 23 and 37, as well as the addition of new claims 39-60. Claims 1-60 are pending.

Information Disclosure Statement

2. The information disclosure statement filed May 4, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each publication or that portion which caused it to be listed. The Information Disclosure Statement filed May 4, 2004 states that copies of the documents cited under "Other Prior Art - Non Patent Literature Documents" were previously submitted to, or cited by, the Office in U.S. Patent Application Serial No. 09/022,990. However, the Information Disclosure Statement filed May 4, 2004 37 does not comply with the requirements of 37 CFR 1.98(d) because copies of the documents cited under "Other Prior Art - Non Patent Literature Documents" in the IDS of U.S. Patent Application Serial No. 09/022,990 were not submitted in that application. The Information Disclosure Statement filed May 4, 2004 has been placed in the application file, but the information referred to therein has not been fully considered.

Claim Objections

3. Claim 24 is objected to because of the following informalities: in line 9, --said-- apparently should be inserted before "nerve". Appropriate correction is required.

4. Claim 39 is objected to because of the following informalities: in lines 5-6, “and apply” apparently should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 6, 23-36, 43, 44 and 48-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the claim language renders the claim indefinite. The limitation “said at least one signal” is recited in line 17 of the claim. This limitation lacks proper antecedent basis in the claim. There is only one signal recited in the claim prior to this recitation. The claim language does not suggest that there may be more than one signal prior to this recitation. Lines 9-10 of the claim recite that a “plurality of electrodes [are] configured to detect a signal”. However, the claim language does not suggest that each electrode of the plurality detects a signal, and no other signals are recited elsewhere in the claim prior to this recitation.

Further regarding the claim language of claim 1, the limitation “at least one electrode” is recited in line 18. It is unclear whether this limitation is intended to refer to the electrodes of the “plurality of electrodes” recited in line 9 of the claim or to some other electrodes not previously referred to in the claim.

Further regarding the claim language of claim 1, the limitation “characteristic of said anatomical site” is recited in line 19. It is unclear whether this limitation is intended to refer to the first anatomical site or the second anatomical site.

Regarding claim 2, the claim language renders the claim indefinite. The limitation “said at least one signal” is recited in line 13 of the claim. This limitation lacks proper antecedent basis in the claim. There is only one signal recited in the claim prior to this recitation. The claim language does not suggest that there may be more than one signal prior to this recitation. Lines 9-10 of the claim recite that a “plurality of electrodes [are] configured to detect a signal”. However, the claim language does not suggest that each electrode of the plurality detects a signal, and no other signals are recited elsewhere in the claim prior to this recitation.

Further regarding the claim language of claim 2, the limitation “characteristic of said anatomical site” is recited in line 15. It is unclear whether this limitation is intended to refer to the first anatomical site or the second anatomical site.

Regarding claim 6, the claim language renders the claim indefinite. The limitation “said at least one signal” is recited in lines 2-3 of the claim. This limitation lacks proper antecedent basis in the claim. There is only one signal recited in claim 3 or 6 prior to this recitation. The claim language does not suggest that there may be more than one signal prior to this recitation. Lines 9-10 of claim 3 recite that a “plurality of electrodes [are] configured to detect a signal”. However, the claim language does not suggest that each electrode of the plurality detects a signal, and no other signals are recited elsewhere in claims 3 or 6 prior to this recitation.

Further regarding the claim language of claim 6, the limitation “at least one electrode” is recited in line 3. It is unclear whether this limitation is intended to refer to the electrodes of the

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“plurality of electrodes” recited in line 9 of claim 3 or to some other electrodes not previously referred to in the claims.

Further regarding the claim language of claim 6, the limitation “characteristic of said anatomical site” is recited in lines 4-5. It is unclear whether this limitation is intended to refer to the first anatomical site or the second anatomical site.

Regarding claim 23, the claim language renders the claim indefinite. The limitation “at least one electrode” is recited in lines 18-19. It is unclear whether this limitation is intended to refer to the electrodes of the “plurality of electrodes” recited in line 10 of claim 23 or to some other electrodes not previously referred to in the claims. The indefinite nature of this claim limitation also raises the potential issue of a gap between method steps. Specifically, there would be nothing in the claim language that links the two steps of the method claim should the limitation “at least one electrode” be interpreted to refer to electrodes other than those of the plurality recited in line 10 of the claim.

Claim 43 recites the limitation “said third anatomical site” in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There is no third anatomical site recited in claims 42 or 43 prior to this recitation.

Regarding claim 48, the claim language renders the claim indefinite. The limitation “at least one electrode” is recited in lines 16-17. It is unclear whether this limitation is intended to refer to the electrodes of the “plurality of electrodes” recited in line 10 of the claim or to some other electrodes not previously referred to in the claim. The indefinite nature of this claim limitation also raises the potential issue of a gap between method steps. Specifically, there would be nothing in the claim language that links steps “(a)” and “(b)” of the method claim

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should the limitation “at least one electrode” in lines 16-17 be interpreted to refer to electrodes other than those of the plurality recited in line 10 of the claim.

Regarding claim 55-60, the claim language renders the claims indefinite. The limitation “at least one electrode” is recited in lines 16-17. It is unclear whether this limitation is intended to refer to the electrodes of the “plurality of electrodes” recited in line 10 of the claims or to some other electrodes not previously referred to in the claims. The indefinite nature of this claim limitation also raises the potential issue of a gap between method steps. Specifically, there would be nothing in the claim language that links steps “(a)” and “(b)” of the method claims should the limitation “at least one electrode” in lines 16-17 be interpreted to refer to electrodes other than those of the plurality recited in line 10 of the claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-5, 7-9, 16, 23 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemmen ('902). Lemmen discloses a sensor comprising a stimulator (14, 16) and a detector (10, 12). The stimulator (14, 16) and detector (10, 12) are connected by a connector (34, 50) and a set screw (62) such that the stimulators and detectors are capable of being automatically positioned at substantially adjacent anatomical sites (See column 4).

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9. Claims 1-3, 6, 7, 13, 16-19, 22-24, 37, 38 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Spitz et al. ('100). Spitz et al. teach a sensor comprising a stimulator (44) shaped to fit a first anatomical site and a detector including a plurality of electrodes (40) shaped to fit a second anatomical site substantially adjacent to the first anatomical site. The stimulator (44) and detector (40) are connected such that they are automatically positioned at substantially adjacent anatomical sites (see Figure 3). The apparatus can be used in any region of the body. The Spitz et al device further includes a processor (30) and a multiplexer (35) that is adapted to select at least one of the plurality of electrodes to detect a signal at the anatomical site.

Allowable Subject Matter

10. Claims 41, 42 and 45-47 are allowable over the prior art of record.

11. Claims 10-12, 14, 15, 20 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claims 25-36, 43, 44 and 49-54 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. Claims 55-60 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

14. Applicant's arguments with respect to the rejection of claims 1-3, 6, 7, 16, 23, 37 and 38 under 35 U.S.C. 102 (b) as being anticipated by Lemmen filed September 20, 2004 have been fully considered but they are not fully persuasive. Applicant contends that Lemmen teaches electrodes which are adjustably positionable with respect to one another using a fixture configured to indicate the distance between the electrodes rather than a connector configured to automatically position the detector substantially adjacent to a second anatomical site when the stimulator is positioned substantially adjacent to a first anatomical site. This argument is not persuasive.

While the Examiner agrees that Lemmen does teach electrodes which are adjustably positionable with respect to one another using a fixture configured to indicate the distance between the electrodes, the Examiner respectfully contends that the connector of Lemmen is configured such that it is fully capable of automatically position the detector substantially adjacent to a second anatomical site when the stimulator is positioned substantially adjacent to a first anatomical site. A set screw (62) disposed on the slide (50) may be used to fix the relative position between electrodes (10, 12 and 14) prior to bringing the electrodes into contact with the skin of the subject, thereby automatically positioning the electrodes (10, 12) substantially adjacent to a second anatomical site when the stimulator (14) is positioned substantially adjacent to a first anatomical site. Therefore, the Lemmen is considered to anticipate independent claims 1, 3 and 23 and the rejections of these claims under 35 U.S.C. 102(b) have been maintained.

Applicant's arguments with respect to the rejection of claim 2 under 35 U.S.C. 102 (b) as being anticipated by Lemmen, filed September 20, 2004, have been fully considered and is persuasive. Lemmen does not appear to teach a sensor with a processor that is adapted to select from the plurality of electrodes at least one electrode detecting at least one signal characteristic of the anatomical site. Therefore, said rejection of claim 2 under 35 U.S.C. 102 (b) as being anticipated by Lemmen has been withdrawn.

15. Applicant's arguments with respect to the rejection of claims 1-6, 13, 16-19, 22, 37 and 38 under 35 U.S.C. 102 (e) as being anticipated by Organ et al. have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Organ et al. teach an array of pairs of current injection electrodes and pairs of voltage measurement electrodes configured to obtain impedance measurements therebetween, respectively, rather than a stimulator configured to generate a stimulus to stimulate a nerve at a first anatomical site and a detector comprising a plurality of electrodes configured to detect a signal generated in response to the stimulus. This argument is moot in view of the new grounds of rejection set forth hereinabove citing Spitz et al. which teach an apparatus with a stimulator configured to generate a stimulus to stimulate a nerve at a first anatomical site, a detector comprising a plurality of electrodes configured to detect a signal generated in response to the stimulus, and a processor with a multiplexer that is adapted to select at least one electrode from the plurality to detect a signal at the anatomical site.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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January 19, 2005